



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/725,373

12/03/2003

Jeffrey Schlom

701461

5890

45733

7590

04/14/2009

LEYDIG, VOIT & MAYER, LTD.
TWO PRUDENTIAL PLAZA, SUITE 4900
180 NORTH STETSON AVENUE
CHICAGO, IL 60601-6731

EXAMINER

DIBRINO, MARIANNE NMN

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

04/14/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/725,373 | Applicant(s) SCHLOM ET AL. | |
| | Examiner DiBrino Marianne | Art Unit 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/23/09 & 10/23/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-50, 53, 54, 56 and 60-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 53, 54, 56, 66-69 is/are allowed.
- 6) ☒ Claim(s) 47-50, 60-65 & 70-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/23/09 has been entered.

Applicant's amendment filed 1/23/09 is acknowledged and has been entered.

2. The terminal disclaimer filed on 10/23/08 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent 7,211,432 has been reviewed and is accepted. The terminal disclaimer has been recorded.

3. Claims 47-50, 53, 54, 56, 58 and newly added claims 66 read on the elected species SEQ ID NO: 2.

In view of Applicant's amendment filed 1/23/09 and Applicant's Terminal Disclaimer cited above, the search has been extended to include SEQ ID NO: 3, 4 and 5. Accordingly, claims 47-50, 53, 54 and 60-73 are presently being examined.

4. Applicant's amendment filed 1/23/09 has overcome the prior rejection of record of claims 52, 58 and 59 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

5. Applicant's amendment filed 1/23/09 has overcome the prior rejection of record of claim 53 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 70-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claims 70-73 recite the limitation "The kit of claim 32" at line 1. There is insufficient antecedent basis for this limitation in the claims since claim 32 has been canceled.

Art Unit: 1644

8. Applicant's amendment filed 1/23/09 has overcome the prior rejection of record of claims 52, 58 and 59 under 35 U.S.C. 102(b) as being anticipated by WO 00/34494 A1.

9. Applicant's amendment filed 1/23/09 has overcome the prior rejection of record of claims 52, 58 and 59 under 35 U.S.C. 102(e) as being anticipated by US 2004/0019195 A1.

10. Applicant's amendment filed 1/23/09 has overcome the prior rejection of record of claims 52, 58 and 59 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,969,609 B1.

11. Applicant's Terminal Disclaimer filed 10/23/08 has over the prior rejection of record of claims 47-49, 58 and 59 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10, 18, 19, 26 and 27 of U.S. Patent No. 7,211,432 (formerly application serial no. 10/406,317).

12. Applicant's Terminal Disclaimer filed 10/23/08 has over the prior rejection of record of claims 50, 52, 54 and 56 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10, 18, 19, 26 and 27 of U.S. Patent No. 7,211,432 (formerly application serial no. 10/406,317) as applied to claims 47-49, 58 and 59 above, and further in view of US 6,319,496 B1 and WO 91/02805 A2.

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 1644

14. Claims 47-49 and 60-65 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3 and 11-15 of copending Application No.11/321,868. Although the conflicting claims are not identical, they are not patentably distinct from each other because the peptide recited in claim 3 of '868 is one of the peptides in the Markush Group recited in instant base claim 47 (*i.e.*, is SEQ ID NO: 2).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 47-49 and 60-65 are directed to an invention not patentably distinct from claims 3 and 11-15 of commonly assigned Application No.11/321,868 as enunciated *supra*.

16. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned Application No.11/321,868, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

17. Claims 53, 54, 56 and 66-73 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-16 of U.S. Patent No. 6,756,038 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the kit of '038 further comprises an immunostimulatory molecule, including one that is GM-CSF (claims 14 and 16, respectively, of '038). With regard to the other immunostimulatory molecules recited in base claim 53 of the instant application, these molecules are obvious variants of immunostimulatory molecules as evidenced by claim 4 of '038, thus it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have included any of them as the immunostimulatory molecule in the kit recited in claim 14 of '038.

Art Unit: 1644

18. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Eileen B. O'Hara, can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marianne DiBrino, Ph.D.
Patent Examiner
Group 1640
Technology Center 1600
March 31, 2009

/G.R. Ewoldt/
Primary Examiner, Art Unit 1644